

REMARKS

Introductory Comments:

Claims 1, 7, 12, 15, 23, 24, 26-29 and 35 were examined in the Office Action mailed August 19, 2004 (the "Office Action"). Claims 15, 23 and 35 were objected to and claims 1, 7, 12, 15, 23, 24, 26-29 and 35 were rejected under 35 U.S.C. §103(a). These objections and rejections are believed to be overcome in part by the above amendments, and are otherwise traversed for the reasons discussed below.

Overview of the Amendments to the Claims:

Claim 15 has been amended to correct an obvious typographical error.

Claim 23 has been canceled.

The amendments made to claim 35 in the previous response are reiterated herein and the claim includes the proper status identifier.

New claims 41 and 42 have been added and correspond to original 15 and 26, respectively.

Objections to the Claims:

Claim 15 was objected to for an obvious typographical error. Claim 15 has been amended to replace the word "if" with the word "is." Thus, this basis for objection has been overcome.

Claim 23 was objected to for failing to further limit the scope of claim 12, from which it depended. Applicants do not agree with the examiner's assertion that "delivering rAAV virions directly to skeletal muscle" is narrower than "introduced via injection into a muscle." Nonetheless, solely in order to facilitate prosecution, Claim 23 has been canceled.

Claim 35 was objected to for failure to include a designation of status as "currently amended." The amendments to claim 35 are therefore reiterated in this response and the status identifier "Currently amended" has been included.

Rejections Under 35 U.S.C. § 103(a):

Claims 1, 7, 12, 23, 24, 26, 29 and 35 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent Publication No. US 2003/0148968 to Hammond et al. (“Hammond”) taken with International Publication No. WO 02/02148 to Gao (“Gao”), and further in view of U.S. Patent No. 6,004,797 to Colosi (“Colosi”).

Claims 7 and 15 were rejected under 35 U.S.C. §103(a) over the combination of Hammond, Gao and Colosi, and further in view of Takeshita et al., *Biochem. Biophys. Res. Comm.* (1996) 227:628-635.

Claim 27 was rejected under 35 U.S.C. §103(a) as being unpatentable over Hammond, Gao and Colosi, and further view of Vuorela et al., *Mol. Hum. Reprod.* (March 2000) 6:276-282 and U.S. Patent Publication No. 2002/0019350 to Levine et al.

Claim 28 was rejected under 35 U.S.C. §103(a) as being unpatentable over Hammond, Gao and Colosi, and further in view of Ashara et al., *Circulation* (1995) 92(9 Suppl.):II365-71. For at least the reasons discussed below, applicants traverse.

Gao is cited in all of the above art rejections. Thus, in order to be valid combinations, Gao must be citable art against the present claims. MPEP 2141.01 states that a prior art reference cited in a rejection under 35 U.S.C. §103 must qualify as prior art under one or more sections of 35 U.S.C. §102. Because Gao was published on January 10, 2002, well after the filing of the instant application on August 17, 2001, it does not qualify as prior art under sections 102(a) or 102(b).

Gao was filed on June 28, 2001, which is before the filing date of the instant application but after the filing date of U.S. Provisional Patent Application No. 60/226,056 (the ‘056 application), filed August 17, 2000, to which the instant application claims priority. Section 102(e) provides that an international application may qualify as prior art as of its filing date under certain specified conditions, i.e. it has an international filing date after November 29, 2000; it designates the United States; and it is published under PCT Article 21(2) in English.¹ See MPEP 706.02(f)(1). In the case of an international application claiming benefit of an earlier-filed U.S. application, the 102(e) date “would

¹ With regard to the remaining sections of 35 U.S.C. § 102, there is no suggestion in the Office Action, nor is it apparent, that Gao could qualify as prior art under any of sections (c), (d), (f) or (g).

be the filing date of the earlier-filed U.S. application, assuming that the earlier-filed application has the proper support for the subject matter relied upon as required by 35 U.S.C. § 119(e) or 120.” MPEP 706.02(f)(1), Example 4. MPEP 2136.03 also clarifies that “the subject matter relied on in the rejection must be disclosed in the earlier-filed application in compliance with 35 U.S.C. 112, first paragraph, in order to give that subject matter the benefit of the earlier filing date under 35 U.S.C. 102(e).”

Gao claims priority to U.S. applications no. 09/607,766 (the ‘766 application, filed June 30, 2000) and 09/826,291 (the ‘291 application, filed April 3, 2001). For the reasons outlined below, however, the specification of the ‘056 application reveals that the subject matter disclosed and claimed in the instant application was invented before June 30, 2000, the earliest date to which Gao claims priority.

The ‘056 application from which the present application claims priority, includes data showing expression of VEGF in rat skeletal muscle that persists at least 10 weeks after injection of rAAV-VEGF vector. These 10-week results are discussed at pages 2, 9, 10 and 12 of the ‘056 application, and illustrated in Figures 3 and 4. (Page numbers refer to the first series of page numbers in the ‘056 application, which comprises two separate pagination ranges.) For example, the “Results” section reveals that “VEGF gene expression was consistently observed at 4 and 10 weeks after injections (Fig. 3).” ‘056 Application at p. 9. The four week (“4W”) and ten week (“10W”) data are presented in Fig. 3. Because the ‘056 application as filed on August 17, 2000 included data obtained 10-weeks after injection, injection must necessarily have taken place before June 8, 2000, which is before Gao’s earliest priority date of June 30, 2000.

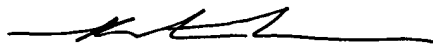
Because the subject matter of the instant application was invented before the earliest filing date to which Gao claims priority, and because all outstanding rejections depend on Gao, withdrawal of the rejections of claims 1, 7, 12, 15, 23, 24, 26-29 and 35 as obvious under 35 U.S.C. §103(a) over the various cited combinations is requested.

CONCLUSION

For the reasons discussed above, applicants submit that claims 1, 7, 12, 15, 23, 24, 26-29, 35 and 41-42 are in proper condition for allowance, and a Notice of Allowance is respectfully requested. If the Examiner notes any further matters which he believes may be resolved by a telephone interview, he is encouraged to contact the undersigned at 650-493-3400.

Respectfully submitted,

Date: February 17, 2005



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